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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/707,685	11/07/2000	Julio C. Palmaz	6006-015	9696

7590 04/25/2005

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EXAMINER

MILLER, CHERYL L

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 04/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	09/707,685	PALMAZ ET AL.	
	Examiner	Art Unit	
	Cheryl Miller	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 39-53 have been considered but are moot in view of the new ground(s) of rejection. The claim for priority to back to November 19, 1999 of US 6,379,383 B1 has been accepted. However, applicant's argument that Whitcher (US 2003/0018381 A1) and Johnson et al. (US 6,533,905 B2) are not prior art has not been found persuasive for the following reasons. Several limitations within both independent claims 39 and 47 contain subject matter not present in the 383' priority application, and therefore, all pending claims are given only the benefit of the current applications filing date, November 7, 2000. Specifically, the limitations, "having a plurality of first structural elements defining a longitudinal axis of the stent and a plurality of second structural elements interconnecting adjacent pairs of first structural elements and defining a circumferential axis of the stent" and "formation of chemical and intra- and inter-granular precipitates" in lines 2-5 and 8-9 of claim 39 and the limitations, "having a plurality of first structural elements defining a longitudinal axis of the stent and a plurality of second structural elements interconnecting adjacent pairs of first structural elements and defining a circumferential axis of the stent" and "formation of chemical and intra- and inter-granular precipitates" and "nickel-titanium having no less than about 51.5 atomic percent nickel" in lines 2-5, 10-11, and 8 respectively in claim 47 are not present in the 383' priority patent, and therefore, the claims receive the benefit of November 7, 2000 only, and therefore, Whitcher and Johnson do qualify as prior art.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 45 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 45 recites the limitation "the deposition rate" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 39-53 are rejected under 35 U.S.C. 102(e) as being anticipated by Whitcher et al. (Pub.No. US 2003/0018381 A1, cited in previous office action). Referring to claim 39, Whitcher discloses a method of manufacturing an endoluminal stent (100) capable of radially expanding from a first diameter to a second diameter and having a plurality of first and second structural elements (fig.2), defining a longitudinal axis and circumferential axis of the stent comprising the steps of vacuum depositing a stent forming metal (120) onto an unpatterned, exterior surface of a generally cylindrical substrate (105) under process conditions (temp, pressure, [0035, 0036,

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0037]) that controls *at least one* of (therefore only one need be disclosed) grain size (Whitcher discloses controlling grain size/crystal structure [0011, 0028, 0038, 0042, 0043]) or formation of chemical and intra and inter-granular precipitates in the bulk material (inherently this is controlled, since Whitcher discloses control of the grain size and boundaries and of the overall crystal structure of the metal; also, because Whitcher discloses selection of a temperature and pressure during deposition, inherently the precipitates are being controlled, since amount and size of the grain/precipitates is dependent upon temp and pressure, upon selection of a temperature and pressure, one has controlled the crystal structure outcome of the metal; also it is noted to the applicant that all the applicant has claimed here is a **condition**. Every condition is a variable, such as deposition rate, temperature, pressure, choice of material, etc, and each condition/variable will have an effect on the crystal structure, such as grain size or granular precipitates of the material. Because Whitcher has disclosed a temperature and pressure, the properties of the material are preselected and are being controlled. The applicant has only a condition, and during deposition, a *condition* is always present. Also, every metal has a specific grain size, grain phase, composition, and binding sites, and just by the user selecting a specific material, the user is controlling the grain size, grain phase, granular precipitates, composition, binding sites, by selection of a material with the desired properties) of a deposited generally tubular, unpatterned, metal film (115), defining the plurality of first and second structural elements of the stent in the unpatterned metal film, and removing the stent from the substrate [0051, 0052, 0053].

Referring to claim 40, Whitcher discloses depositing a sacrificial material layer (130) onto the substrate (105) prior to vacuum deposition and removing the sacrificial layer in order to remove the stent from the substrate [0053].

Referring to claims 41-45, Whitcher discloses vacuum deposition by ion beam assisted evaporation, sputtering, in the presence of an inert gas [0034, 0035, 0036, 0037].

Referring to claim 45, Whitcher discloses a deposition rate no less than 20 nm/sec ([0035], > 0.05 mm/min).

Referring to claim 46, Whitcher discloses rotation of the substrate during deposition ([0035], rotate or translate the substrate).

Referring to claim 47, Whitcher discloses a method of making an endoluminal stent (100) comprising vacuum depositing [0034, 0035, 0036, 0037] nickel and titanium [0062] onto an exterior surface of a generally cylindrical substrate (105) to form a generally tubular film of nickel-titanium having no less than about 51.5 atomic percent nickel [0066], table 1, the deposition occurring under process conditions that control *at least one* of (therefore only one need be disclosed) grain size (Whitcher discloses controlling grain size/crystal structure [0011, 0028, 0038, 0042, 0043]) and formation of inter and intra-granular precipitates in the bulk material (inherently this is controlled, since Whitcher discloses control of the grain size and boundaries and of the overall crystal structure of the metal; also, because Whitcher discloses selection of a temperature and pressure during deposition, inherently the precipitates are being controlled, since amount and size of the grain/precipitates is dependent upon temp and pressure, upon selection of a temperature and pressure, one has controlled the crystal structure outcome of the metal; also it is noted to the applicant that all the applicant has claimed here is a **condition**).

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Every condition is a variable, such as deposition rate, temperature, pressure, choice of material, etc, and each condition/variable will have an effect on the crystal structure, such as grain size or granular precipitates of the material. Because Whitcher has disclosed a temperature and pressure, the properties of the material are preselected and are being controlled. The applicant has only a condition, and during deposition, a *condition* is always present. Also, every metal has a specific grain size, grain phase, composition, and binding sites, and just by the user selecting a specific material, the user is controlling the grain size, grain phase, granular precipitates, composition, binding sites, by selection of a material with the desired properties) of the nickel-titanium film, and removing the stent from the substrate [0051, 0052, 0053].

Referring to claims 48, 50, and 51, Whitcher discloses a nickel-titanium composition between *about* 51.5 and 55.0 atomic percent nickel, wherein the nickel and titanium is a binary nickel-titanium alloy (table 1), [0062, 0066].

Referring to claim 49, Whitcher discloses the rotation of the substrate during deposition (vector A, [0048]).

Referring to claims 52 and 53, Whitcher discloses imparting a pattern onto the exterior surface of the substrate (105), wherein the pattern is transferred to the film during deposition [0055, 0056], and alternatively, imparting a pattern onto the tubular film after deposition [0054].

Claims 39-40, 42, and 46-53 are rejected under 35 U.S.C. 102(e) as being anticipated by Johnson et al. (USPN 6,533,905 B2, cited in previous office action). Referring to claim 39, Johnson discloses a method of manufacturing an endoluminal stent capable of radially expanding from a first diameter to a second diameter and having a plurality of first and second structural

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elements (fig.9; col.1, lines 10-15), defining a longitudinal axis and circumferential axis of the stent comprising the steps of vacuum depositing (col.4, lines 52-53; col.5, lines 19-20) a stent forming metal onto an unpatterned, exterior surface of a generally cylindrical substrate (10; col.3, lines 62-67) under process conditions that control at least one of grain size or formation of chemical inter and intra-granular precipitates in the bulk material (it is noted to the applicant that all the applicant has claimed here is a **condition**. Every condition is a variable, such as deposition rate, temperature, pressure, choice of material, etc, and each condition/variable will have an effect on the crystal structure, such as grain size or granular precipitates of the material. Because Johnson has disclosed a temperature and pressure, the properties of the material are preselected and are being controlled. The applicant has only a condition, and during deposition, a *condition* is always present. Also, every metal has a specific grain size, grain phase, composition, and binding sites, and just by the user selecting a specific material, the user is controlling the grain size, grain phase, granular precipitates, composition, binding sites, by selection of a material with the desired properties) of a deposited generally tubular, unpatterned metal film, defining the plurality of first and second structural elements of the stent in the unpatterned metal film, and removing the stent from the substrate (col.4, lines 21-31; col.5, lines 62-67).

Referring to claim 40, Johnson discloses depositing a sacrificial material layer (14) onto the substrate (10) prior to vacuum deposition and removing the sacrificial layer in order to remove the stent from the substrate (col.4, lines 24-31).

Referring to claim 42, Johnson discloses vacuum deposition by sputtering (col.5, lines 25-29).

Referring to claim 46, Johnson discloses rotation of the substrate during deposition (col.4, lines 48-53).

Referring to claim 47, Johnson discloses a method of making an endoluminal stent (fig.9) comprising vacuum depositing nickel and titanium (col.4, lines 54-65; col.3, lines 25-29) onto an exterior surface of a generally cylindrical substrate (10) to form a generally tubular film of nickel-titanium having no less than about 51.5 atomic percent nickel (col.4, lines 54-65; col.3, lines 25-29; col.5, lines 1-13) wherein the deposition is under process conditions that control *at least one* of grain size or formation of chemical inter and intra-granular precipitates in the bulk material (it is noted to the applicant that all the applicant has claimed here is a **condition**. Every condition is a variable, such as deposition rate, temperature, pressure, choice of material, etc, and each condition/variable will have an effect on the crystal structure, such as grain size or granular precipitates of the material. Because Johnson has disclosed a temperature and pressure, the properties of the material are preselected and are being controlled. The applicant has only a condition, and during deposition, a *condition* is always present. Also, every metal has a specific grain size, grain phase, composition, and binding sites, and just by the user selecting a specific material, the user is controlling the grain size, grain phase, granular precipitates, composition, binding sites, by selection of a material with the desired properties) and removing the stent from the substrate (col.5, lines 62-67).

Referring to claims 48, 50, and 51, Johnson discloses a nickel-titanium composition between about 51.5 and 55.0 atomic percent nickel, wherein the nickel and titanium is a binary nickel-titanium alloy (col.4, lines 54-65; col.3, lines 25-29; col.5, lines 1-13).

Referring to claim 49, Johnson discloses the rotation of the substrate during deposition (col.4, lines 48-53).

Referring to claims 52 and 53, Johnson discloses imparting a pattern onto the exterior surface of the substrate (col.6, lines 36-50), wherein the pattern is transferred to the film during deposition, and alternatively, imparting a pattern onto the tubular film after deposition (col.6, lines 19-22).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Cheryl Miller



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